PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	IMPLEMENTATION OF PATIENT REPORTED OUTCOME MEASURES AND PATIENT REPORTED EXPERIENCE MEASURES IN MELANOMA CLINICAL QUALITY REGISTRIES: A SYSTEMATIC REVIEW
AUTHORS	Blood, Zachary; Tran, Anh; Caleo, Lauren; Saw, Robyn; Dieng, Mbathio; Shackleton, Mark; Soyer, H. Peter; Arnold, Chris; Mann, Graham; Morton, Rachael

VERSION 1 – REVIEW

REVIEWER	Elizabeth D. Drugge, PhD, MPH New York Medical College USA
REVIEW RETURNED	07-Aug-2020

GENERAL COMMENTS	This is a valuable piece of work that will contribute to the management and treatment of melanoma. My only comment relates to references at the end of Table 1 (numbers 19 & 21). I look forward to the integration and utility of PROMs & PREMs in the MelCOR registry!

REVIEWER	Angela M. Stover, PhD University of North Carolina at Chapel Hill, USA
REVIEW RETURNED	09-Oct-2020

GENERAL COMMENTS	Thank you for the opportunity to review the paper, “Implementation of PROMs and PREMs in melanoma clinical quality registries: a systematic review.” This is a nicely written paper. The authors conducted a systematic review consistent with PRISMA standards through Dec. 2017, and then updated to Feb. 2020. The authors present PROMs and PREMs used in clinical quality registries for people with early-stage cutaneous melanoma, frequency and method of collection, participant recruitment methods, and funding models for each registry to inform a new Australian Melanoma Clinical Outcomes Registry. 14 studies identified 4 registries. Seven commonly used PROMs were reported (universal and melanoma-specific) and 1 PREM. The authors concluded that clinical registries indicate PROMs/PREMs for melanoma care can be incorporated and address important gaps, however cost and collection bias may limit generalizability. Abstract Add the cutoff date of Feb 2020 and that the grey literature was also searched, with government reports and digital theses included

	Add that two melanoma patients provided feedback. It's uncommon to have patients involved in systematic reviews and this is a strength of the study (could add to discussion as well). Spell out EQ-5D acronym Some of your secondary outcome measures are not mentioned in results: How they are collected, frequency of collection, participant recruitment methods and funding models for each registry Pg 3 strengths and limitations section could be more specific and better reflect abstract and discussion. Introduction Consider adding a sentence or two about how clinical registries are used in healthcare typically at the group level (e.g., quality assessment, large-scale research platforms, etc.) and why PROMs/PREMs enhance what already exists in registries Methods Pg. 5, lines 42-45: please describe what qualitative data was collected in the registry example and how it informed targeted programs: "Qualitative data collected by this registry has resulted in tailored strategies and targeted programs to address important gaps in patient care." Will you collect qualitative data in the new registry? Pg. 5, lines 51-54: "The search strategy included patients treated for cutaneous melanoma of any stage." Please provide a justification for all stages since the intent for use is with early stage melanoma and symptoms/QOL may vary by stage. Pg. 5, line 56: take out reference to "Appendix 1" from this paragraph and add to pg. 6, lines 38-54 instead to improve clarity/organization Pg. 7, lines 28-31: add details on how patients enhanced study so others can replicate Pg. 7, line 49 mentions Table 2. Table 1 isn't mentioned until page 8 in results section. Results Pg. 8, line 33: Were all of these registries from published literature or some from grey literature? Were any registries excluded? And if so, why? Pg. 10, line 3: spell out EQ-5D, add citations for PROMs to text Pg. 11, lines 13-18: add citations for PROMs Discussion One of your secondary outcome measures seem to be missing from the discussion: funding models for each registry PROMs and PREMs used in the existing registries reflect differences in where PROMs were developed (EORTC developed in EU and used in EU registries, U.S. registry uses PROMIS). Consider mentioning that calibrated PROMs assessing similar constructs can be cross-walked so it is not necessary for all registries to select identical measures to be comparable. Some of the registries collected PREMs that lack validity and reliability evidence. Consider exploring why in the discussion and how registries could mitigate non-standardized questionnaires. Based on your results, what are the next steps for the new Australian Melanoma Clinical Outcomes registry in terms of your primary and secondary outcome findings? Will you now evaluate the PROMs and PREMs from the identified registries? What do you recommend for others developing melanoma registries with

	PROMs and PREMs and what are recommended future directions for registries? Pg. 13, lines 14-26: paper collection has its own challenges. Other options may be registry staff calling patients who do not complete online, or interactive voice response systems (do not require internet access) Pg. 15, lines 3-21: it may not be possible to use registries in routine care visits if the registry is a separate system from the electronic health record (which is frequently the case). Additionally, registries have typically been used for group-level data (quality, benchmarking) but individual patient care requires better reliability from the PROMs (>0.70 reliability for groups and 0.90 for individuals). You could mention that a future direction for registries may be to develop registries within EHRs so all the systems are linked.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Comments to the Author
This is a valuable piece of work that will contribute to the management and treatment of melanoma. My only comment relates to references at the end of Table 1 (numbers 19 & 21). I look forward to the integration and utility of PROMs & PREMs in the MelCOR registry!
Response: The references for Table 1 have been updated. See page 25.

Reviewer: 2

Comments to the Author
Thank you for the opportunity to review the paper, “Implementation of PROMs and PREMs in melanoma clinical quality registries: a systematic review.” This is a nicely written paper. The authors conducted a systematic review consistent with PRISMA standards through Dec. 2017, and then updated to Feb. 2020. The authors present PROMs and PREMs used in clinical quality registries for people with early-stage cutaneous melanoma, frequency and method of collection, participant recruitment methods, and funding models for each registry to inform a new Australian Melanoma Clinical Outcomes Registry. 14 studies identified 4 registries. Seven commonly used PROMs were reported (universal and melanoma-specific) and 1 PREM. The authors concluded that clinical registries indicate PROMs/PREMs for melanoma care can be incorporated and address important gaps, however cost and collection bias may limit generalizability.

Abstract
Add the cutoff date of Feb 2020 and that the grey literature was also searched, with government reports and digital theses included Add that two melanoma patients provided feedback. It’s uncommon to have patients involved in systematic reviews and this is a strength of the study (could add to discussion as well).
Response: Thank you, we have added these points to the Abstract, see page 2.

Spell out EQ-5D acronym
Some of your secondary outcome measures are not mentioned in results: How they are collected, frequency of collection, participant recruitment methods and funding models for each registry
Response: We have spelt out the EQ-5D acronym on pages 2 &10.
The PRMs collection method, frequency, participant recruitment and funding for each registry are

included in Table 2 (pages 26-27).

Pg 3 strengths and limitations section could be more specific and better reflect abstract and discussion.
Response: Thank you, we have revised this section – see pages 3-4.

Introduction
Consider adding a sentence or two about how clinical registries are used in healthcare typically at the group level (e.g., quality assessment, large-scale research platforms, etc.) and why PROMs/PREMs enhance what already exists in registries
Response: We have revised the Introduction section on page 5, paragraph 2, to incorporate these suggestions.

Methods
Pg. 5, lines 42-45: please describe what qualitative data was collected in the registry example and how it informed targeted programs: “Qualitative data collected by this registry has resulted in tailored strategies and targeted programs to address important gaps in patient care.” Will you collect qualitative data in the new registry?
Response: Thank you for pointing out our error in the use of the term “Qualitative” data. We meant “additional” data used in the economic and impact evaluations of the PCOR. We have amended this statement to read; “Data collected by this registry has resulted in tailored strategies and targeted programs to address important gaps in patient care.” We have also provided two references giving examples of how the PCOR data has been used.

We do not plan to collect qualitative data in the new Melanoma Clinical Outcomes Registry (MelCOR), however in our evaluation of the registry we will interview key stakeholders about the feasibility and acceptability of all data variables, including patient reported measures.

Pg. 5, lines 51-54: “The search strategy included patients treated for cutaneous melanoma of any stage.” Please provide a justification for all stages since the intent for use is with early stage melanoma and symptoms/QOL may vary by stage.
Response: We agree that symptoms and quality of life may differ by stage of melanoma, however to maximise the number of potential identifiable registries covering melanoma we did not exclude those that included patients with later-stage disease. We were unsure whether all registries, especially PROMs registries would include sufficient detail about stage or sub-stage, particularly if based on patient self-reports. Furthermore, we were aware that common psychosocial issues (such as fear of cancer recurrence; and anxiety due to insufficient information about treatment options and costs of care) exist across melanoma stages, as highlighted by Winstanley and colleagues (2013 & 2020).
Winstanley J, White E, Boyle F, Thompson J. What are the pertinent quality-of-life issues for melanoma cancer patients? Aiming for the development of a new module to accompany the EORTC core questionnaire. Melanoma Res. 2013;23(2):167-174.
Winstanley J, White E, Saw R, Young T, Burmeister B, Nikolic D, Busto-Cornide I, Iglesias-Pena N, Boyle F. Development of the Melanoma Concerns Questionnaire (MCQ-28); refinement of the EORTC QLQ-MEL38 module. Psychooncology. 2020 Feb;29(2):321-330. doi: 10.1002/pon.5251.

Pg. 5, line 56: take out reference to “Appendix 1” from this paragraph and add to pg. 6, lines 38-54 instead to improve clarity/organization Pg. 7, lines 28-31: add details on how patients enhanced study so others can replicate. Pg. 7, line 49 mentions Table 2. Table 1 isn’t mentioned until page 8 in results section.
Response: Thank you, we have modified all of these points as requested. See page 7, paragraph 1; page 8, paragraph 1; and information about consumer input added to page 7, paragraph 2. Table 1 is now mentioned ahead of Table 2, see first paragraph in the results, page 10 on the marked copy.

Results
Pg. 8, line 33: Were all of these registries from published literature or some from grey literature? Were any registries excluded? And if so, why?
Response: All identified registries were from the published literature. The search of grey literature did not reveal any additional registries. See revised Results section page 10, paragraph 1. No registries were excluded – however a note regarding the role of the Eindhoven cancer registry as a vehicle to recruit patients for the PROFILEs registry has been added.

Pg. 10, line 3: spell out EQ-5D, add citations for PROMs to text Pg. 11, lines 13-18: add citations for PROMs
Response: Thank you we have added this information as requested. See page 11, paragraph 1. All citations to PROMs have been added to the text – see Results pages 11-13.

Discussion
One of your secondary outcome measures seem to be missing from the discussion: funding models for each registry PROMs and PREMs used in the existing registries reflect differences in where PROMs were developed (EORTC developed in EU and used in EU registries, U.S. registry uses PROMIS).
Response: Funding of registries is reported in Table 2, pages 26-27 and is emphasised in the Discussion section page 16, paragraph 1.

Consider mentioning that calibrated PROMs assessing similar constructs can be cross-walked so it is not necessary for all registries to select identical measures to be comparable.
Response: Thank you, we agree and have added this point to the Discussion section, see page 13, paragraph 3.

Some of the registries collected PREMs that lack validity and reliability evidence. Consider exploring why in the discussion and how registries could mitigate non-standardized questionnaires.
Response: As independent validation of the instruments was outside the scope of this review, we can only report on those that were or were not validated. We do not wish to speculate as to why invalidated measures were used. However we acknowledge that this is an important area for further research, and have added this point to the Discussion section (See page 14, paragraph 1)

Based on your results, what are the next steps for the new Australian Melanoma Clinical Outcomes registry in terms of your primary and secondary outcome findings? Will you now evaluate the PROMs and PREMs from the identified registries? What do you recommend for others developing melanoma registries with PROMs and PREMs and what are recommended future directions for registries?
Response: We have expanded our Discussion to include future plans for MelCOR, see page 17, paragraph 2.

Pg. 13, lines 14-26: paper collection has its own challenges. Other options may be registry staff calling patients who do not complete online, or interactive voice response systems (do not require internet access) Pg. 15, lines 3-21: it may not be possible to use registries in routine care visits if the registry is a separate system from the electronic health record (which is frequently the case).
Response: We agree and have added both of these points. See page 14, paragraph 3; and page 17, paragraph 2.

Additionally, registries have typically been used for group-level data (quality, benchmarking) but individual patient care requires better reliability from the PROMs (>0.70 reliability for groups and 0.90 for individuals). You could mention that a future direction for registries may be to develop registries within EHRs so all the systems are linked.

Response: As mentioned in the response point above, we agree and have added this point to the Discussion section on page 17, paragraph 2.

VERSION 2 – REVIEW

REVIEWER	Angela M. Stover, PhD University of North Carolina at Chapel Hill, USA
REVIEW RETURNED	29-Jan-2021

GENERAL COMMENTS	Thank you for responding to reviewer (and editor) comments. The paper flows better now and reviewer concerns have been addressed.